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Ortho Molecular Products Inc. 3017 Business Park Drive PO, Box 1060 Stevens Point, WI 54481 715.342.9881 Prione 800.332.2351 715.342.9866 Fax orthomolecularproducts.com Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

MAY 25 20

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Gastrointestinal Support

Dietary Ingredients: Cape Aloe, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Super Aloe 250

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

Muissa Dager

Ortho Molecular Products

975 0162 LET 16227



Ortho Molecular Products Inc.

3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715.342.9881 Phone 800.332.2351 715.342.9866 Fax

orthomolecular products.com

Attachment of Super Aloe 250 Labels

Suggested Use: As a dietary supplement, 1 capsule at bedtime (allow 24 hours before redusing) or as recommended by your health care professional Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors.

Nonce: For occasional use only This product contains Cape Aloe (Aloe Ferox). Do not use this if you develop diarrhea or abdominal pain. Consult your health professional if you have frequent diarrhea (Do NOT USE IF PREGNANT.) Nursing mothers should contact their health professionals.

As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion Keep container tightly closed. Store at room temperature. Keep out of reach of children. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or



5 Label ID L-OMP100-821100-8



Super Aloe 250



Supplement Facts

Serving Size: 1 Capsule Servings Per Container: 100

1 capsule contains	Ámount Per % Daily Serving Value
Cape Aloe	250 mg *
التكريب وبالبائيات الشروال	
* % Dally Value not e	stablished

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon

Milg. by Ortho Microcular Products, inc. 3017 Business Park Drive. Stevens Point, WI. 54481

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